In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1229V

(not to be published)

* *	Special Master Corcoran
MISTI FRASER, *	
*	Filed: August 9, 2019
Petitioner, *	
*	Hepatitis A and B vaccines;
v. *	Raynaud's Phenomenon;
*	Reactive Arthritis; Case
SECRETARY OF HEALTH AND *	Reports; Diagnosis; Lack of
HUMAN SERVICES, *	Expert Report
*	
Respondent. *	
*	
* *	

Mark T. Sadaka, Sadaka Associates LLC, Englewood, NJ, for Petitioner.

Glenn A. MacLeod, U.S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On September 12, 2017, Misti Fraser filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program")[2]. *See generally* Petition (ECF No. 1) ("Pet."). Petitioner alleges that she developed Raynaud's phenomenon ("Raynaud's") and/or reactive arthritis after receipt of the Hepatitis A and/or B ("Hep A" and "Hep B") vaccines on September 18, 2014. *Id.* at 1.

Petitioner has filed medical records and two items of scientific and medical literature in support of her claim, but did not file an expert report. After a preliminary review of the case's file, I informed the parties that I intended to resolve this matter on the record. To that end, Petitioner filed a motion for ruling

[1] Although this Decision has not formally been designated for publication, it will ultimately be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). **This means the ruling will be available to anyone with access to the internet**. As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published Decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire Decision will be available in its current form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-10 through 34 (2012)) (hereinafter "Vaccine Act" or "the Act"). All subsequent references to sections of the Vaccine Act shall be to the pertinent subparagraph of 42 U.S.C. § 300aa.

on the record on March 8, 2019 (ECF No. 25) ("Mot."), Respondent opposed that motion on April 5, 2019 (ECF No. 27) ("Opp."), and Petitioner filed a reply on April 10, 2019 (ECF No. 29) ("Reply"). Having completed my review of the evidentiary record and the parties' filings, I hereby DENY Petitioner's request for compensation. As discussed below, the record clearly establishes that Petitioner has Raynaud's (although it does not substantiate her claim of reactive arthritis). She has offered scant evidence, however, to establish that her actual injury could be, or was, caused by the Hep A or B vaccines. The overall record supporting her claim in this case is simply too thin for a favorable entitlement decision.

I. Factual Background

Before receiving the vaccines at issue in this case, Ms. Fraser had a history of endometriosis and food allergies. On March 6, 2014 (six months before the administration of the Hep A and B vaccines), Petitioner received inactivated polio and yellow fever vaccines at the Vanderburgh County Health Department in Evansville, Indiana, but declined any others. Ex. 1 at 1, 4, filed Sept. 15, 2017 (ECF No. 7-1). She later informed a treater that she had been "feeling fatigued" since that time, along with experiencing a cough for the past six weeks, and was prescribed antibiotics. Ex. 2 at 12, filed Sept. 15, 2017 (ECF No. 7-2).

Petitioner (then age forty-six) received the vaccines in question on September 18, 2014, at the Vanderburgh County Health Department. Ex. 1 at 5–6; Ex. 5 at 1, filed May 14, 2018 (ECF No. 17-1). She thereafter complained (as set forth in the Petition[3]) that she began to notice a significant loss of circulation in her hands about three weeks later (or around October 9, 2014), followed by blistering on her hands plus a cold sore on her upper lip. Pet. at 1–2. No immediately-contemporaneous medical records corroborate these symptoms, however.

The medical record is thereafter silent for over four months, until January 30, 2015, when Ms. Fraser saw Dr. Michael Allen at St. Mary's Physicians' Health Group ("SMPHG") in Evansville. *See* Ex 2. at 10–12. At this time, she expressed the concern that she had an autoimmune disease, and complained of symptoms, starting in October, and consisting of blisters on her hands, a feeling "like she lost circulation," and a cold sore on her top lip. *Id.* at 10, 11. She also reported lesions on several fingers, which waxed and waned, plus two episodes during which her distal fingers turned white, something Dr. Allen deemed "consistent with Raynaud's."[4] *Id.* at 11. The record from the January 2015 visit reflects Ms. Fraser's report that "all of her symptoms seem to start after September 18," the date on which she had received the Hep A and B vaccines. *Id.* The "Vaccines" section of this visit record also notes that Petitioner had received the Hep A and B vaccines on September 18, 2014. *Id.*

On exam, Petitioner displayed a cold sore on her left upper lip, and had skin changes on the medial aspect of several fingers "consistent with dyshidrotic eczema." Ex. 2 at 12. In addition, lab

[3] Petitioner never filed a declaration or affidavit in support of her claim.

[4] Raynaud's is characterized by bilateral ischemia of the fingers, toes, ears, or nose, along with severe pallor and paresthesias and pain, brought on by cold temperatures or emotional stimuli, and is usually attributed to underlying disease or an anatomical abnormality. *Dorland's Illustrated Medical Dictionary* 1430 (32nd ed. 2012) (hereinafter "*Dorland's*").

testing performed on January 30th showed a positive ANA[5] at a titer of 1:160 with normal results for rheumatoid factor, erythrocyte sedimentation rate, and scleroderma antibodies, leading Dr. Allen to assess it as "likely not significant," although he expressed the intent to measure it again to see if it changed. *Id.* at 22–24. Dr. Allen diagnosed Ms. Fraser with Raynaud's, vesicular eczema of the hands, and herpes labialis, prescribing an antiviral medication. *Id.* at 12.

Over a year later, on April 25, 2016, Petitioner returned to SMPHG for an annual physical exam. As the "chief complaint" section of the visit states, Ms. Fraser sought in part to discuss "hands/feet going numb." Ex. 2 at 7. She also reported mouth ulcers, "arthralgias/joint pain (generalized aches)," body tingles, and fatigue, along with the Raynaud's symptoms observed in January. *Id.* at 9. On exam, Petitioner was noted to have "dusky fingertips with cold in room," and although her joint exam was normal, with no tenderness and normal motion, she was referred to a rheumatologist for "symptoms of Raynaud's which seem to be getting worse." *Id*. Lab testing performed at this time again showed a positive ANA (at a titer of 1:320), but with normal results for other markers of inflammation. *Id.* at 19–22.

The following month, on May 24, 2016, Petitioner saw Dr. Erin Arnold, a rheumatologist, and informed her of the purported reaction to the Hep A and B vaccines, which she timed as having begun within two months of the mid-September vaccinations. She added that she had begun to experience tingling two months ago, and also that she felt stressed and very tired. Ex. 3 at 12, filed Sept. 15, 2017 (ECF No. 7-3). On exam, Ms. Fraser revealed tenderness over the hamstring insertion in the medial posterior right knee. Her rheumatologic exam was otherwise normal in all joints and the spine, however, with no swelling, synovitis, tenderness, or decreased range of motion. She did at this time also display Raynaud's symptoms affecting the right hand, although the exam findings were not described. *Id.* at 14. Dr. Arnold diagnosed Petitioner with Raynaud's, stiffness of unspecified joints, paresthesias, and a positive ANA. *Id*. at 14, 16. Lab testing ordered by Dr. Arnold, and performed on May 25, 2016, again showed a positive ANA, but also a positive HLA-B27 (a biomarker suggesting a genetic susceptibility for spondyloarthropathies),[6] although all other testing for autoimmune serologies produced normal results. *Id.* at 18-22.

Petitioner went back to Dr. Arnold on June 2, 2016, now reporting pain affecting her cervical spine, hands, hips, and sacroiliac joints, but that was alleviated by over-the-counter non-steroidal inflammatory medications, and which otherwise did not interfere with her activities of daily living. Ex. 3 at 7. On exam, Ms. Fraser displayed tenderness of her bilateral metacarpophalangeal joints and

[5] ANA stands for "antinuclear antibodies." *Dorland's* at 70. Positive ANA titers are associated with autoimmune rheumatologic diseases like lupus. *Johnson v. Sec'y of Health & Human Servs.*, No. 14-254V, 2018 WL 2051760, at *14 n.24 (Fed. Cl. Spec. Mstr. Mar. 23, 2018).

[6] The spondyloarthropathies (SpAs) are a family of degenerative inflammatory joint disorders, include ankylosing spondylitis (AS), reactive arthritis, and psoriatic arthritis. *Dorland's* at 1754. They are strongly associated with the HLA-B27 antigen. *Godfrey v. Sec'y of Health & Human Servs.*, No. 10-565V, 2015 WL 10710961, at *2–3 (Fed. Cl. Spec. Mstr. Oct. 27, 2015), *mot. for review denied*, slip op., Apr. 29, 2016 (ECF No. 109). The HLA-B27 biomarker is present in about 80–95% of patients with ankylosing spondylitis, although it is also present in 6% of the general U.S. population (and less than 5% of Caucasians who are positive for the biomarker also have SpA). As a result, a positive test for HLA-B27 alone is not diagnostic for an SpA. *Godfrey*, 2015 WL 10710961, at *2.

wrists, but seemed otherwise normal from a rheumatologic standpoint. *Id.* at 8–9. Dr. Arnold informed Petitioner of the significance of her spondyloarthropathy biomarker (noting without elaboration that it could reflect a "shot reaction"), and diagnosed her with Raynaud's, sacroiliitis, and unspecified joint stiffness—but not with any other formal arthritic condition (including those associated with her HLA-B27 biomarker), and ordered an MRI of the pelvis, asking Ms. Fraser to return in three months. *Id.* at 10–11.

Ms. Fraser followed up with Dr. Arnold that fall, at the end of October 2016. *See* Ex. 3 at 1–6. She reported that she was taking a "holistic approach" to treatment, avoiding taking medication she had been previously prescribed, and stating her desire not to have imaging testing performed due to its expense. *Id.* at 1. Dr. Arnold's notes in the medical record from this visit observed that Petitioner appeared much better overall, but had developed migratory joint pains affecting her elbows, fingertips, toes, and sometimes her knees, along with arthralgias affecting her ankles, wrists, hands, hips, and knees made worse by "stress and food." *Id.* Her examination at this time revealed tenderness of both hands, both knees, both ankles, and both feet without limitation of motion or swelling, as well as right-sided cervical spine tenderness with a minimally decreased range of motion. *Id.* at 3. She was diagnosed with abnormal immunological blood serologies, Raynaud's, and joint stiffness—but (again) *not* with reactive arthritis or any other kind of spondyloarthropathy. *Id.* at 4.

The most recent medical record filed in this case and relevant to the claim[7] is from February 9, 2017, when Ms. Fraser returned to SMPHG, complaining that she had autoimmune disease that her specialist (presumably Dr. Arnold) was purportedly not treating effectively. Ex. 2 at 3. She also complained of nausea, increasing fatigue, and generalized achiness, and noted as well that she had been told that she had HLA-B27 genotype "induced by the hepatitis B vaccine," with Raynaud's symptoms beginning six weeks after vaccine administration. *Id.* at 6. She was now taking turmeric (a spice with reported anti-inflammatory qualities), for her symptoms, and claimed some benefit, but no prescribed medications. *Id.* After exam, Petitioner was again diagnosed with Raynaud's and fatigue but no other rheumatologic disease. *Id.* at 7.

II. Procedural History

It took approximately seven months for Petitioner to file the medical records most relevant to the claim's resolution. Thereafter, Respondent filed his Rule 4(c) Report objecting to a damages award on May 30, 2018. ECF No. 18. I subsequently held a status conference with the parties on June 13, 2018, after which I ordered Petitioner to file an expert report in support of her petition on or before August 31, 2018. *See* Non-PDF Order, issued June 13, 2018. This deadline was extended several times at Petitioner's request, but no expert report was ultimately filed. Rather, on December 21, 2018, Ms. Fraser represented her desire to confer with counsel about how she wished to proceed. Eventually, I directed her to file either a motion for a ruling on the record, or a motion to dismiss her case, by March 8, 2019. The result was the currently-pending motion for ruling on the record, which is now fully ripe

[7] As Respondent noted in his ruling on the record opposition, the final two medical record exhibits Petitioner filed are gynecology records not directly relevant to her vaccine injury claim. Opp. at 2 n.1 (citing Ex. 6; Ex. 7). Petitioner also filed a record from March 2017 that references her Raynaud's but mainly involved treatment of an ear issue. Ex. 2 at 1–3.

for resolution.

III. Parties' Respective Arguments

In her initial brief, Petitioner argues that she can satisfy all three of the prongs of the test set by the Federal Circuit in *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). First, she proposes that "the literature provides copious evidence" that Raynaud's can be vaccine-caused—although she cites only to a single case report in support. *See* V. Selvaraj, et al., *A Rare Case of Raynaud's Vasculitis Secondary to Hepatitis B Vaccination: The Induced Auto-Immune Attack Syndrome*, 1 Case Reports in Internal Med. 17 (2014), filed as Ex. 9 (ECF No. 24-2) ("Selvaraj"). Next, she maintains that her theory is corroborated by the medical record, which not only establishes the fact of injury but evidence of an ongoing inflammatory process (seen in the persistent positive ANA findings). Mot. at 6–7. In so arguing, she suggests that Petitioner's generalized joint aches were diagnosed later as reactive arthritis—although the record, as reviewed above, does not corroborate this assertion, as it contains no evidence establishing she ever received that diagnosis (as opposed to Raynaud's). *Id.* at 6. Finally, she maintains her onset of symptoms—two weeks for Raynaud's, and three weeks for reactive arthritis—was medically reasonable. *Id.* at 6–7.

In opposition, Respondent concedes that Petitioner was properly diagnosed with Raynaud's, but otherwise contests her entitlement to a damages award. Opp. at 10. Regarding the Raynaud's side of the claim, Respondent maintains that she has not established that the Hep A or B vaccine could cause the condition, instead largely relying on the temporal association between vaccination and onset. *Id.* at 12–13. He notes that she only offers Selvaraj in support of the "can cause" prong, and observes that the article itself hedges when proposing a causal relationship. *Id.* at 15–16, 19–20. He further proposes that the record does not support the contention that the vaccines caused her Raynaud's symptoms, arguing that her consistently positive ANA is not evidence of an ongoing inflammatory process. *Id.* at 19–20. Finally, Respondent maintains that her symptoms more likely than not began six to eight weeks after vaccination at earliest, base on record evidence from the spring of 2016 (discounting statements she made in January 2015). *Id.* at 17.

With respect to reactive arthritis as the injury, Respondent stresses the absence of evidence from the medical record supporting such a diagnosis, beyond the fact that Petitioner was positive for the HLA-B27 biomarker. Opp. at 11–12, 18–19. Otherwise, Respondent argues that Petitioner has not offered preponderant evidence establishing that the relevant vaccines can cause reactive arthritis, discounting the value of the single item of literature Petitioner filed[8] for this aspect of her claim. *Id.* at 14–15 (referencing J. Pope, et al., *The Development of Rheumatoid Arthritis After Recombinant Hepatitis B Vaccination*, 25:9 J. Rheum 1687 (1998), filed as Ex. A (ECF No. 28-1)_. And (similar to his attack on the Raynaud's symptoms), Respondent posits that the record does not suggest the vaccines caused any autoimmune response as evidenced by chronic inflammation, and also that the timing of symptoms that might arguably

[8] Petitioner in fact only filed the article's abstract, but Respondent filed the entire article in connection with opposing the motion for ruling on the record.

support a reactive arthritis diagnosis were far too long after vaccination to be medically reasonable. *Id.* at 18.

Ms. Fraser filed a brief reply in which she largely emphasizes what record evidence exists supporting her contention that the Hepatitis A or B vaccine could cause Raynaud's (as reflected by Selvaraj), and that it did do so, in a timeframe within three weeks of vaccination. Reply at 1–2.

IV. Applicable Law

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[9] In this case, Petitioner does not assert a Table claim.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

[9] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C.*, 704 F.3d at 1356.[10]

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and statements of a treating physician do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert

[10] Although decisions like *Contreras* suggest that the burden of proof required to satisfy the first *Althen* prong is less stringent than the other two, there is ample contrary authority for the more straightforward proposition that when considering the first prong, the same preponderance standard used overall is also applied when evaluating if a reliable and plausible causal theory has been established. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1350 (Fed. Cir. 2010).

testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Dept. of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. App'x 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Law Governing Analysis of Fact Evidence*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd sub nom. Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir.

2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs.*, No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. denied sub nom. Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *Lalonde v. Sec'y of Health & Human Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not every filed item factors into the outcome of this decision. While I have reviewed all of the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Human Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

D. *Resolution of Case Via Ruling on Record*

I proposed to resolve this matter on the papers, rather than by holding a hearing, and the parties did not object to this manner of resolution. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.*, No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs*., 38 Fed. Cl. 397, 402–03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Cl. Ct. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. The Record Does not Establish that Petitioner Has Reactive Arthritis

The medical record does not support Petitioner's contention that she experienced "reactive arthritis," or some other form of spondyloarthropathy, precluding any claim that the mid-September 2014 vaccines she received caused that injury. No treater ever so diagnosed her. At most, Petitioner has consistently been found to possess biomarkers that are *associated* with SpAs but are not alone a sufficient basis for such a diagnosis. *See supra* note 6. The fact that Dr. Arnold noted the significance of the presence of these biomarkers to Petitioner in June 2016 does not establish she had reactive arthritis. And Dr. Arnold's "shot reaction" notation (which presumably Petitioner would emphasize as both establishing diagnosis as well as connecting the September 2014 vaccinations to this claimed injury) is vague and ultimately not corroborated by other records. Absent proof of a cognizable injury, this component of Petitioner's claim fails. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1346 (Fed. Cir. 2010).

Moreover, even if Ms. Fraser had been formally diagnosed with some kind of spondyloarthropathy (and assuming that she had made a more robust showing that the vaccines she received could cause such an injury), her claim would clearly fail on the third *Althen* prong. There is no evidence of even the kind of initial symptoms, like joint pain, that could arguably suggest the existence of an arthritic condition before *April 2016*, eighteen months from vaccination. Ex. 2 at 7. Such a record does not allow for the conclusion (especially where Petitioner offers no reliable expert opinion) that the vaccines Petitioner received in September 2014 could have caused her long-after symptoms. And Petitioner's claims (which appear only in the Petition and are not corroborated by a declaration or affidavit) that such symptoms began a few weeks later are utterly unsubstantiated. Nor did Petitioner establish that her Raynaud's symptoms would be related to these other alleged symptoms, or that they would be understood to be preliminary manifestations of an autoimmune process leading to a spondyloarthropathy.

II. Petitioner's Raynaud's-Based Claim Cannot be Established with Preponderant Evidence

As recognized by Respondent, the record establishes that Petitioner has Raynaud's. But she cannot prevail on this side of her claim either, for the simple reason that she has not satisfied any of the three *Althen* prongs with preponderant evidence.

First, Petitioner has not preponderantly established that the Hep A or B vaccine could cause Raynaud's. She offers no expert to set forth a causation theory. Certainly this is not fatal to her claim in and of itself, since Program petitioners are not obligated to marshal an expert's assistance in every case. Section 13(a)(1)(B) (preponderant showing may be met "by medical records *or* by medical opinion") (emphasis added). But to support her argument, she offers only a *single* item of literature—Selvaraj—which by its own terms says less about causation than what Petitioner needed to succeed. Thus, Selvaraj acknowledges that "no causative link between administration of the [Hep B] vaccine and the occurrence of an adverse event" has been demonstrated by medical science. Selvaraj at 18. It is also a single-patient case study—a type of evidence that has limited probative value in the Vaccine Program (although I do not discount it out of hand). *Doe/16 v. Sec'y of Health & Human Servs.*, No. 06-670, 2008 WL 2390064, at *14 (Fed. Cl. Spec. Mstr. June 2, 2008) (citing *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993) ("[c]ausal attribution based on case studies must be regarded with caution, largely because they lack control and thus do not provide the level of information or detail found in epidemiologic studies")). Selvaraj is too thin a reed to rely on to meet the preponderant test required to establish the "can cause" first *Althen* prong.

Second, the record itself does not support the conclusion that Petitioner's Raynaud's symptoms were most likely caused by either vaccine she received. Although the diagnosis is supported by the medical record, no treater ever proposed that Ms. Fraser's symptoms were due to vaccination (even though it does appear she personally *believed* this to possibly be the case). There is also no evidence (other than the symptoms themselves) that Petitioner was experiencing a vaccine-induced reaction between September 2014 and her doctor's visit in January 2015. As Respondent has pointed out, the facts of this case are not congruent with the Selvaraj patient's experience, since his onset was sooner, and accompanied not only by a positive ANA but "evidence of a systemic inflammatory process," along with imaging that

confirmed the presence of widespread vasculitis. Opp. at 19 (quoting Selvaraj at 18). An expert opinion, or reference to well-reasoned prior Program decisions consistent with the present facts, could have aided Petitioner's evidentiary showing, but neither was offered.

Admittedly, Petitioner's showing on the third *Althen* prong is slightly better, and perhaps just barely sufficient to be preponderant. Thus, from the January 2015 record it could be concluded that onset of her Raynaud's-related symptoms not only began in the fall of 2014 (as Petitioner reported at that time), but in a time somewhat consistent with the Selvaraj case study for when vaccine-induced Raynaud's would be expected to begin. Although Respondent has pointed out subsequent records that suggest a longer post-vaccination onset, it would be reasonable to give the closer-in-time record more weight. But even if I found in favor of Petitioner on this *Althen* prong (and notably I would be doing so without Petitioner *herself* ever filing an affidavit in support of her claim, as the Act requires (*see* Section 11(c)(1)), her failure to establish that the Hep A or B vaccine could, or did, likely cause her Raynaud's would still defeat her claim.

Conclusion

Despite a general lack of evidence, Petitioner's claim is hardly frivolous. Unquestionably she suffers from Raynaud's, and the single item of literature she offered was consistent with her causation theory. With better additional medical or scientific literature, if not a competent expert, plus some corroborative record proof (including stronger treater support), or reference to other Program decisions that suggest the reasonableness of the theory proposed, it is readily conceivable that a similarly-situated petitioner could substantiate a comparable claim based on a demonstrated case of post-vaccination Raynaud's. But that showing was not made in this case, therefore compelling me to DISMISS the claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk **SHALL ENTER JUDGMENT** in accordance with this decision.[11]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Special Master

[11] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.